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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/648,494  | 08/25/2003  | Etan S. Chatlynne    | ETH-5040            | 4244             |
| 7590  | 01/29/2007  |                      | EXAMINER            |                  |
| Ralph W. Selitto, Jr.<br>McCarter & English<br>Four Gateway Center<br>100 Mulberry Street<br>Newark, NJ 07102 |             |                      | ADAMS, AMANDA S     |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3731                |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE  | MAIL DATE   | DELIVERY MODE        |                     |                  |
| 3 MONTHS  | 01/29/2007  | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/648,494             | CHATLYNNE ET AL.    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Amanda Adams           | 3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 November 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1- is/are pending in the application.
- 4a) Of the above claim(s) 41 is/are withdrawn from consideration.
- 5) Claim(s) 39-41 is/are allowed.
- 6) Claim(s) 1-8, 24-27, 30-35 is/are rejected.
- 7) Claim(s) 9-23, 28, 29 and 36-38 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-3, 27, and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Kay (US 5,662,683).
3. Regarding **claims 1 and 33**, Kay discloses the invention substantially as claimed including a winding means capable of winding a suture or cord around a helical member in a helical path such that the suture is attached to at least one turn of the helical member (fig. 6).
4. Regarding **claims 2 and 3**, Kay discloses a casing in which the winding means is rotatably mounted to the casing, and that is sized and shaped to be gripped by a surgeon ([34]).
5. Regarding **claim 27**, Kay discloses a supporting means for supporting the helical member during the winding of the suture around the helical member (fig. 7 [42]).

### ***Claim Rejections - 35 USC § 103***

6. **Claims 4-7 and 24-26, 34, and 35** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kay (US 5,662,683) in view of Nunez (US 5,232,204).

7. **Regarding claims 4, 24, and 34,** Kay discloses that the winding means is a winding tube rotatable about an axis and movable in an axial direction in response to its rotational movement (col. 4, lines 49-55). As the winding tube is rotated, the helical anchor is driven into tissue, which causes the winding tube to also move closer to the surface of the tissue, which means that it moves in an axial direction.

8. However, in the alternative that the applicant argues that the winding tube in the device of Kay does not have to move in a longitudinal or axial direction in response to its rotation, Nunez teaches an inner tube with helical threads formed thereon (24) and an outer tube (12) with helical threads to mate with those threads of the inner tube, wherein upon rotation of the tube, the tube is moveable in an axial direction. The application of the screw threads provides additional control over the amount of longitudinal movement. Therefore it would have been obvious to combine the threads of Nunez with the device of Kay.

9. **Regarding claims 5-7, 25, 26, and 35,** Kay discloses a winding tube that includes securing means for securing at least one portion of the suture thereto so as to cause the suture to wind about the helical member that is a groove in the winding tube that is angled in a direction opposite to the direction of the winding tubes' rotation and that is capable of receiving at least one portion of the suture therein (fig. 7, groove [44] is angled longitudinally along the tube, and the axis of rotation is along this same

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longitudinal axis, which means that the direction of rotation is perpendicular to, and therefore opposite to, the groove).

10. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kay (US 5,662,683) in view of Nunez (US 5,232,204).

11. **Regarding claim 8**, see discussion regarding claim 4 for a full explanation.

12. **Claims 30-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kay (US 5,662,683) in view of Jervis (WO 00/28902).

13. **Regarding claim 30**, Kay discloses the invention substantially as claimed including a support rod extending from the distal end of the winding means, but fails to disclose that the support rod extends through the winding means. However, Jervis teaches a support rod (fig. 6 [20]) that extends through the winding means ([10]). This provides stabilizing support as it does not have to rotate with the winding tube and improves deployment of the helical member. Therefore it would have been obvious have the support rod of Kay extend all the way through the winding tube instead of extending only from the distal end.

14. **Regarding claim 31**, Kay further discloses that the support rod portion of the winding tube has a distal end shaped and sized to engage the helical member by a friction fit (fig. 7, [42], [44], and [17]). Therefore, if the device of Kay is modified such that this support rod is a distinguishable component from the winding tube, then it would have been obvious for it to have this same friction fit size and shape.

15. **Regarding claim 32**, the length of the support rod can be lengthened to accommodate additional helical members. See *In re Harza*, 274 F. 2d 669, 124 USQP

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378 (CCPA 1960). The modification of the length of this device to accommodate additional parts does not change the function of the device. Therefore it would have been obvious to make this modification.

***Allowable Subject Matter***

16. **Claims 9-23** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art, alone or in combination discloses or suggests all of the limitations of claim 9. The closest prior art of Bolduc et al (US 5,824,008) teaches gears operated by an actuator, however the winding tube would no longer be moveable in an axial direction in response to its rotation if these gears were added to the device of Kay. Claims 10-23 are depending from claim 9 and therefore are also indicated as allowable subject matter.

18. **Claims 28 and 29** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

19. The following is a statement of reasons for the indication of allowable subject matter: No combination of references discloses or teaches the device substantially as claimed. Adding the guide tube of Jervis with a spiral member on the end of the guide

tube teaches away from the guide tube being rotatably mounted in the winding means as taught by Kay in view of Nunez, because it would move axially upon rotation, and the device of Jervis does not permit that motion.

20. **Claims 36-38** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 37 and 38 are contain allowable subject matter for the same reasons as claims 28 and 29, in addition to the following:

21. The guide tube of Jervis is not moveable in an axial direction relative to the winding tube. To have it moveable axially would change the function of the device of Jervis. Claim 38's subject matter is allowable because it depends from claim 37.

22. **Claims 39-41** are allowed.

23. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art discloses using a device with the structure of claims 39-41 for the method of winding a suture about a helical member. The closest relevant prior art is Collier et al (US 2003/0195562), which discloses that a suture is wrapped about a coiled helical member, but does not disclose the method of how. Craig (US 6,626,917) discloses that a thread is pulled along a helical path, but not that it is wrapped around the helical member. Kay does not disclose the use of sutures. Claims 40 and 41 are allowable because they are dependent from claim 39.

#### ***Response to Arguments***

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24. Applicant's arguments, filed on 11/6/06 with respect to claims 1, 33, and 39 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection has been made as described above.

25. Amendments to the objections regarding claim 2 as well as the claim numbering have been considered and the objections by the examiner have been withdrawn.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA ASA 11/18/07

*Glenn*  
GLENN K. DAWSON  
PRIMARY EXAMINER